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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,454	12/19/2000	Steven R. Wiley	2968-B	8855

22932 7590 03/26/2002

IMMUNEX CORPORATION
LAW DEPARTMENT
51 UNIVERSITY STREET
SEATTLE, WA 98101

EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,454	WILEY, STEVEN R.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *fax cover sheet* .

DETAILED ACTION

Claims **1-45** are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is accepting a Fax Response for Written Restriction Requirements. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, drawn solely to a method of modulating angiogenesis with a TWEAK receptor antagonist, classified in class 424, subclass 184.1, 130.1.

II. Claims 1-4, 24-27, drawn solely to a method of modulating angiogenesis with a TWEAK receptor agonist, classified in class 424, subclass 184.1, 130.1.

III. Claims 28-30, 43, 45 drawn to an antagonist polypeptide, classified in class 530, subclass 300, 350.

IV. Claims 31-34, 44 drawn to nucleic acids, vectors, host cells and method of producing a TWEAK receptor antagonist, classified in class 435, subclass 320.1, 325, 69.1, and class 536, subclass 23.5.

(Claim 35 improperly comprised three independent methods- and is thus separated into three Groups as listed below.)

V. Claims 35-38, in part, drawn solely to a method of identifying a test compound that binds to a TWEAK receptor extracellular domain, wherein the test compound is not TWEAK, classified in class 435, subclass 4.

VI. Claim 35-38, in part, drawn solely to a method of identifying a test compound that affects the interaction between a TWEAK and a TWEAK receptor, classified in class 435, subclass 7.8.

VII. Claims 35-38, in part, drawn solely to a method of identifying a test compound that modulates the interaction between a TWEAK receptor and a TRAF, classified in class 435, subclass 4.

VIII. Claim 39, drawn to a method of modulating the binding of TWEAK to the TWEAK receptor, classified in class 424, subclass 184.1, 130.1.

IX. Claims 40-42, drawn to a method for targeting a detectable label or chemotherapeutic to vascular tissue comprising contacting vascular tissue with an antibody that binds TWEAK receptor, classified in class 424, subclass 1.49.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups III-IV represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups I-II, V-IX are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Group III and the methods of Groups I-II, VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antagonist products as claimed can be used in a materially different process such as affinity chromatography.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the

reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

SPECIES ELECTIONS

GROUP I:

Claim 6 is generic to a plurality of disclosed patentably distinct species comprising the following:

a) soluble receptor fragments, b) antibodies, c) antisense, d) triple helix forming nucleic acids, e) peptides, f) small molecules.

In the event that "soluble receptor fragments" are elected above, Claim 8 will be subject to the species below:

a) an FC polypeptide and about 2 to 4 polypeptides comprising a TWEAK receptor extracellular domain or fragments or variants thereof capable of binding TWEAK

b) a leucine zipper domain and about 2 to 4 polypeptides comprising a TWEAK receptor extracellular domain or fragments or variants thereof capable of binding TWEAK

c) a peptide linker and about 2 to 4 polypeptides comprising a TWEAK receptor extracellular domain or fragments or variants thereof capable of binding TWEAK

In the event that species "a" above is selected Claims 10-11 will be subject to further species election:

a) TWEAK receptor extracellular domain comprises amino acids 28-79 of SEQ ID NO:7

b) TWEAK receptor extracellular domain comprises amino acids 28-309 of SEQ ID NO:7

Group I (Claims 17-18) are further generic to a plurality of disclosed patentably distinct species comprising the following:

a) ocular neovascularization, b) solid tumor

Group I (Claims 21-23) are further generic to a plurality of disclosed patentably distinct species comprising any ONE of the chemotherapeutic agents as listed in claims 21-23. Applicant must elect only one species of the distinct agents.

GROUP II:

Claim 27 is generic to a plurality of disclosed patentably distinct species comprising the following distinct disorders or diseases or surgical procedures:

a) coronary artery disease, b) myocardial ischemia, c) myocardial infarction, d) angina pectoris, e) peripheral circulation deficits, f) limb ischemia/reperfusion injury, g) enhancement of wound healing, h) organ transplantation, i) reconnection of severed digits or limbs, j) vascular skin grafting, k) bypass surgery, or l) angioplasty

GROUP III:

Claim 28 is generic to a plurality of disclosed patentably distinct species comprising the following distinct species of antagonists:

a) an FC polypeptide and a TWEAK receptor extracellular domain or fragment or variant thereof capable of binding TWEAK

b) a leucine zipper domain and a TWEAK receptor extracellular domain or fragment or variant thereof capable of binding TWEAK

c) a peptide linker and a TWEAK receptor extracellular domain or fragment or variant thereof capable of binding TWEAK

Group III (Claims 29-30) are further generic to a plurality of disclosed patentably distinct species comprising the following distinct peptides:

a) TWEAK receptor extracellular domain comprises amino acids 28-79 of SEQ ID NO:7

b) TWEAK receptor extracellular domain comprises amino acids 28-309 of SEQ ID NO:7

GROUPS V, VI, and VII:

Claims 37 and 38 are generic to a plurality of disclosed patentably distinct species comprising the following modulators:

a) wherein the modulation is stimulatory

b) wherein the modulation is inhibitory

GROUP VIII:

Claims 39 is generic to a plurality of disclosed patentably distinct species comprising the following distinct peptides:

a) a polypeptide comprising a soluble TWEAK receptor extracellular domain

b) an antibody that binds to the TWEAK receptor extracellular domain

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues. Further, the steps and reagents of the above species are completely distinct and impart different biological functions and uses such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues. Additionally, the species incorporating diseases and or disorders differ at least in etiology, pathology, and mechanisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
March 11, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600